

Appl. No. : 10/826,028
 Filed : April 16, 2004

AMENDMENTS TO THE CLAIMS

1. (Original) A method for treating ischemic congestive heart failure in a patient comprising the steps of:

- identifying akinetic tissue within a heart chamber wall;
- making an incision through the akinetic tissue in the chamber wall;
- inserting a shaping device into the chamber through the incision, said shaping device comprising a compliant material;
- removing the shaping device; and
- closing the incision.

2. (Original) The method of Claim 1 further comprising the step of excluding the akinetic tissue.

3. (Original) The method of Claim 1 further comprising the step of at least partially securing to the chamber wall, a patch comprising a superelastic or shape memory material.

4. (Original) The method of Claim 1 further comprising the step of drawing a vacuum to compress said shaping device for insertion or removal.

5. (Original) The method of Claim 1, wherein the step of making an incision comprises using an endoscope with an incising tip.

6. (Original) The method of Claim 1, wherein the step of inserting a shaping device comprises using an endoscope to place the shaping device within the chamber.

7. (Original) The method of Claim 1, wherein the shaping device does not require inflation.

8. (Original) The method of Claim 1, wherein the shaping device is self-expanding.

9. (Original) The method of Claim 1, wherein the shaping device comprises a material that is substantially not translucent.

10. (Original) The method of Claim 1, wherein the shaping device comprises a material that is substantially translucent.

11. (Original) The method of Claim 1, wherein the shaping device comprises a color that contrasts with the natural color of cardiac tissue to make it more visible.

12. (Original) The method of Claim 1, wherein the shaping device comprises nitinol.

13. (Original) The method of Claim 1, wherein the shaping device comprises a superelastic or shape memory material.

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14. (Original) The method of Claim 1, wherein said shaping device comprises a plurality of sections, at least one of which may be removable to vary the size and or shape of the shaping device.

15. (Original) The method of Claim 1, wherein said shaping device is configured to form one of a plurality of selectable sizes and/or shapes.

16. (Original) The method of Claim 15, wherein said shaping device comprises a means for selectively forming one of said plurality of shapes and/or sizes.

17. (Original) The method of Claim 16, wherein said means comprises an adjustable component with perforations that facilitate adjusting the size or shape of said shaping device.

18. (Original) The method of Claim 1, wherein the step of inserting a shaping device comprises moving the shaping device relative to a sheath so as to permit the shaping device to assume a natural size and shape.

19. (Original) The method of Claim 14, wherein the shaping device can assume one of two or more sizes selectable by moving the shaping device different distances relative to the sheath.

20. (Original) The method of Claim 1, wherein the step of inserting a shaping device comprises moving the shaping device relative to an endoscope so as to permit the shaping device to assume a natural size and shape.

21. (Original) The method of Claim 14, wherein the shaping device can assume one of two or more sizes selectable by moving the shaping device different distances relative to the endoscope.

22. (Original) The method of Claim 1, wherein the shaping device is deployable through a surgical instrument.

23. (Original) The method of Claim 1, wherein the step of identifying akinetic tissue comprises providing one or more images to a computer.

24. (Original) The method of Claim 1 further comprising the steps of providing one or more images to a computer, and using the computer to determine when to perform the method.

25. (Original) The method of Claim 24, wherein images of the heart at different time intervals can be saved.

26. (Original) The method of Claim 24, wherein two or more persons using different computers can view the model.

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27. (Original) The method of Claim 1 further comprising the steps of providing one or more images to a computer, and using the computer to determine an appropriate size for one or more devices.

28. (Original) The method of Claim 27, wherein the computer is used to determine an appropriate size for the shaping device.

29. (Original) A method for treating ischemic congestive heart failure in a patient comprising the steps of:

- identifying akinetic tissue within a heart chamber wall;
- making an incision through the akinetic tissue in the chamber wall;
- inserting a shaping device into the chamber through the incision, said shaping device being configured to self-expand when released within the ventricle;
- removing the shaping device; and
- closing the incision.

30. (Original) The method of Claim 29 further comprising the step of excluding the akinetic tissue.

31. (Original) The method of Claim 29 further comprising the step of initiating a closing suture while the shaper is inside the chamber thereby bringing the kinetic tissue closer together to improve the size and shape of the chamber.

32. (Original) The method of Claim 29, wherein the step of making an incision comprises using an endoscope with an incising tip.

33. (Original) The method of Claim 29, wherein the step of inserting a shaping device comprises using an endoscope to place the shaping device within the chamber.

34. (Original) The method of Claim 29, wherein the shaping device comprises nitinol.

35. (Original) The method of Claim 29, wherein the shaping device comprises a superelastic or shape memory material.

36. (Original) The method of Claim 29 further comprising the step of drawing a vacuum to compress said shaping device for insertion or removal.

37. (Original) The method of Claim 29, wherein the shaping device comprises a material that is substantially not translucent.

38. (Original) The method of Claim 29, wherein the shaping device comprises a material that is substantially translucent.

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39. (Original) The method of Claim 29, wherein the shaping device comprises a color that contrasts with the natural color of cardiac tissue to make it more visible.

40. (Original) The method of Claim 29, wherein the step of inserting a shaping device comprises moving the shaping device relative to a sheath so as to permit the shaping device to assume a natural size and shape.

41. (Original) The method of Claim 40, wherein the shaping device can assume one of two or more sizes selectable by moving the shaping device different distances relative to the sheath.

42. (Original) The method of Claim 29, wherein the step of inserting a shaping device comprises moving the shaping device relative to an endoscope so as to permit the shaping device to assume a natural size and shape.

43. (Original) The method of Claim 40, wherein the shaping device can assume one of two or more sizes selectable by moving the shaping device different distances relative to the endoscope.

44. (Original) The method of Claim 29, wherein the shaping device is deployable through a surgical instrument.

45. (Original) The method of Claim 29, wherein the step of identifying akinetic tissue comprises providing one or more images to a computer.

46. (Original) The method of Claim 29 further comprising the steps of providing one or more images to a computer, and using the computer to determine when to perform the method.

47. (Original) The method of Claim 46, wherein images of the heart at different time intervals can be saved.

48. (Original) The method of Claim 46, wherein two or more persons using different computers can view the model.

49. (Original) The method of Claim 29 further comprising the steps of providing one or more images to a computer, and using the computer to determine an appropriate size for one or more devices.

50. (Original) The method of Claim 49, wherein the computer is used to determine an appropriate size for the shaping device.

51. (Original) A method for treating ischemic congestive heart failure in a patient comprising the steps of:

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identifying akinetic tissue within a heart chamber wall;

making an incision through the akinetic tissue in the chamber wall;

inserting a single component shaping device into the chamber through the incision, wherein said shaping device comprises a compliant material and is configured to be placed inside the heart chamber to help prevent the result of a chamber that is too small;

at least partially excluding the akinetic tissue;

removing the shaping device; and

closing the incision.

52. (Original) The method of Claim 51, wherein the step of inserting a shaping device comprises moving the shaping device relative to a sheath so as to permit the shaping device to assume a natural size and shape.

53. (Original) The method of Claim 51, wherein the shaping device can assume one of two or more sizes selectable by moving the shaping device different distances relative to the sheath.

54. (Original) A device for treating cardiac afflictions comprising a collapsible shaper made of a compliant material configured to expand without inflation, wherein said device is shaped to define a more idealized shape of a heart chamber when in a substantially expanded state.

55. (Original) The device of Claim 54 further comprising a plurality of sections, at least one of which may be removable to vary the size and/or shape of the shaper.

56. (Original) The device of Claim 54, wherein said device is configured to form one of a plurality of selectable sizes and/or shapes.

57. (Original) The device of Claim 56 further comprising a means for selectively forming one of said plurality of shapes and/or sizes.

58. (Original) The device of Claim 57, wherein said means comprises an adjustable component with perforations that facilitate adjusting the size or shape of said shaping device.

59. (Original) The device of Claim 54, wherein said shaper is configured to fit snugly and temporarily within said heart chamber during a surgical procedure.

60. (Original) The device of Claim 54, wherein said shaper comprises only one member.

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61. (Original) The device of Claim 54, wherein said shaper comprises a monolithic shape.

62. (Original) The device of Claim 54, further comprising means for releasing and expanding said shaper.

63. (Original) The device of Claim 62, wherein the means for releasing and expanding said shaper comprises an internal shaft and an external shaft configured such that relative movement of said shafts causes said shaper to expand.

64. (Original) The device of Claim 63, wherein said shaper can be expanded to more than one size by continuing to move the inner shaft forward.

65. (Original) The device of Claim 63, wherein said external shaft comprises an endoscope.

66. (Original) The device of Claim 54, wherein said shaper is configured to be released and to self-expand after placement into a heart chamber.

67. (Original) The device of Claim 54, wherein said shaper comprises nitinol.

68. (Original) The device of Claim 54, wherein said shaper comprises a superelastic or shape memory material.

69. (Original) The device of Claim 54, further comprising sheets of reinforcing material wherein said sheets are configured to strengthen the walls of the shaper.

70. (Original) The device of Claim 69, wherein the reinforcing sheets have a petal-like arrangement and are in contact with the shaper walls.

71. (Original) The device of Claim 70, wherein said petals are located on the interior of the shaper walls.

72. (Original) The device of Claim 70, wherein said petals are located on the exterior of said shaper walls.

73. (Original) The device of Claim 70, wherein said petals are located within said shaper walls.

74. (Original) The device of Claim 54, further comprising one or more reinforcing wires.

75. (Original) The device of Claim 54, further comprising one or more reinforcing strips.

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76. (Original) The device of Claim 54, further comprising one or more reinforcing mandrels.
77. (Currently amended) The ~~method~~ device of Claim 54, wherein the shaping device comprises a material that is substantially translucent.
78. (Currently amended) The ~~method~~ device of Claim 54, wherein the shaping device comprises a color that contrasts with the natural color of cardiac tissue to make it more visible.
79. (Original) The device of Claim 54, wherein said shaper is substantially cone shaped.
80. (Original) A surgical device comprising a compressible and expandable shaper made of a compliant material that is inherently resistant to permanent deformation.
81. (Original) The device of Claim 80, wherein said shaper is substantially cone shaped.
82. (Original) A device for treating cardiac afflictions comprising a single component shaper made of a compliant material, wherein said device is configured to be placed inside a heart chamber during a procedure to help prevent the result of a chamber that is too small.
83. (Original) The device of Claim 82, wherein said shaper does not require inflation.
84. (Original) The device of Claim 82, further comprising means for releasing and expanding said shaper.
85. (Original) The device of Claim 84, wherein the means for releasing and expanding said shaper comprises an internal shaft and an external shaft configured such that relative movement of said shafts causes said shaper to expand.
86. (Original) The device of Claim 85, wherein said shaper can be expanded to more than one size by continuing to move the inner shaft forward.
87. (Original) The device of Claim 85, wherein said external shaft comprises an endoscope.
88. (Original) The device of Claim 82, wherein said shaper is configured to be released and to self-expand after placement into a heart chamber.
89. (Original) The device of Claim 82, wherein said shaper comprises a material that is inherently resistant to permanent deformation.
90. (Original) The device of Claim 82, further comprising sheets of reinforcing material wherein said sheets are configured to strengthen the walls of the shaper.

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91. (Original) The device of Claim 82, further comprising one or more reinforcing wires.
92. (Original) The device of Claim 82, further comprising one or more reinforcing strips.
93. (Original) The device of Claim 82, further comprising one or more reinforcing mandrels.
94. (Original) The device of Claim 82, wherein the shaping device comprises a material that is substantially not translucent.
95. (Original) The device of Claim 82, wherein said shaper is substantially cone shaped.
96. (Original) A device for treating cardiac afflictions comprising a shaper made of a compliant material, wherein said device is shaped to conform more closely to the natural shape of a heart chamber and wherein said device partially encloses an interior space such that fluids may flow freely from within and without.
97. (Original) The device of Claim 96, wherein said shaper is configured to fit snugly and temporarily within said heart chamber during a surgical procedure.
98. (Original) The device of Claim 96, further comprising means for releasing and expanding said shaper.
99. (Original) The device of Claim 98, wherein the means for releasing and expanding said shaper comprises an internal shaft and an external shaft configured such that relative movement of said shafts causes said shaper to expand.
100. (Original) The device of Claim 96, wherein a vacuum can be used to collapse the shaper for insertion or removal.
101. (Original) The device of Claim 99, wherein said external shaft comprises an endoscope.
102. (Original) The device of Claim 96, wherein said shaper comprises a material that is inherently resistant to permanent deformation.
103. (Original) The device of Claim 96, further comprising sheets of reinforcing material wherein said sheets are configured to strengthen the walls of the shaper.
104. (Original) The device of Claim 96, further comprising one or more reinforcing wires.

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105. (Original) The device of Claim 96, further comprising one or more reinforcing strips.

106. (Original) The device of Claim 96, further comprising one or more reinforcing mandrels.

107. (Currently amended) The method device of Claim 96, wherein the shaping device comprises a color that contrasts with the natural color of cardiac tissue to make it more visible.

108. (Original) The device of Claim 96, wherein said shaper is substantially cone shaped.

109. (Original) A device for treating cardiac afflictions comprising a compressible shaper configured to self-expand, wherein said device is shaped to define a more optimal shape of a heart chamber when in a substantially expanded state.

110. (Original) The device of Claim 109, wherein said shaper is configured to fit snugly and temporarily within said heart chamber during a surgical procedure.

111. (Original) The device of Claim 109, wherein a vacuum can be used to collapse the shaper for insertion or removal.

112. (Original) The device of Claim 109, wherein said shaper comprises more than one layer.

113. (Original) The method of Claim 109, wherein the shaping device comprises a material that is substantially not translucent.

114. (Original) The method of Claim 109, wherein the shaping device comprises a color that contrasts with the natural color of cardiac tissue to make it more visible.

115. (Original) The device of Claim 109, further comprising means for releasing and expanding said shaper.

116. (Original) The device of Claim 115, wherein the means for releasing and expanding said shaper comprises sheath such that moving the shaper relative to the sheath causes the shaper to expand.

117. (Original) The device of Claim 116, wherein said sheath comprises an endoscope.

118. (Original) The device of Claim 116, wherein the shaper can assume one of two or more sizes selectable by moving the shaping device different distances relative to the sheath.

119. (Original) The device of Claim 109, wherein said shaper comprises nitinol.

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120. (Original) The device of Claim 109, wherein said shaper comprises a superelastic or shape memory material.

121. (Original) The device of Claim 109, further comprising sheets of reinforcing material wherein said sheets are configured to strengthen the walls of the shaper.

122. (Original) The device of Claim 121, wherein the reinforcing sheets have a petal-like arrangement and are in contact with the shaper walls.

123. (Original) The device of Claim 122, wherein said petals are located on the interior of the shaper walls.

124. (Original) The device of Claim 122, wherein said petals are located on the exterior of said shaper walls.

125. (Original) The device of Claim 122, wherein said petals are located within said shaper walls.

126. (Original) The device of Claim 109, further comprising one or more reinforcing wires.

127. (Original) The device of Claim 109, further comprising one or more reinforcing strips.

128. (Original) The device of Claim 109, further comprising one or more reinforcing mandrels.

129. (Original) The device of Claim 109, wherein said shaper is substantially cone shaped.

130. (Original) A device for reconstructing an organ chamber comprising a shaper that can be configured to define a more optimal shape of the organ chamber, said shaper comprising a plurality of sections, at least one of which may be removable to vary the size and/or shape of the shaper.

131. (Original) A method for treating a heart related ailment in a patient comprising the steps of:

identifying akinetic tissue within a heart chamber wall;

making an incision through the akinetic tissue in the chamber wall;

inserting a shaping device into the chamber through the incision, said shaping

device comprising a compliant material;

removing the shaping device; and

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closing the incision.

132. (Original) The method of Claim 131, wherein said heart related ailment comprises congestive heart failure.

133. (Original) The method of Claim 131, wherein said heart related ailment comprises ischemic congestive heart failure.

134. (Original) The method of Claim 131, wherein said heart related ailment comprises heart failure associated with regional wall-motion abnormality.

135. (Original) A method for treating a heart related ailment in a patient comprising the steps of:

- identifying akinetic tissue within a heart chamber wall;
- making an incision through the akinetic tissue in the chamber wall;
- inserting a shaping device into the chamber through the incision, said shaping device being configured to self-expand when released within the ventricle;
- removing the shaping device; and
- closing the incision.

136. (Original) The method of Claim 135, wherein said heart related ailment comprises congestive heart failure.

137. (Original) The method of Claim 135, wherein said heart related ailment comprises ischemic congestive heart failure.

138. (Original) The method of Claim 135, wherein said heart related ailment comprises heart failure associated with regional wall-motion abnormality.

139. (Original) A method for treating a heart related ailment in a patient comprising the steps of:

- identifying akinetic tissue within a heart chamber wall;
- making an incision through the akinetic tissue in the chamber wall;
- inserting a single component shaping device into the chamber through the incision, wherein said shaping device comprises a compliant material and is configured to be placed inside the heart chamber to help prevent the result of a chamber that is too small;
- at least partially excluding the akinetic tissue;
- removing the shaping device; and

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closing the incision.

140. (Original) The method of Claim 139, wherein said heart related ailment comprises congestive heart failure.

141. (Original) The method of Claim 139, wherein said heart related ailment comprises ischemic congestive heart failure.

142. (Original) The method of Claim 139, wherein said heart related ailment comprises heart failure associated with regional wall-motion abnormality.

143. (Original) A method of adjusting the size and/or shape of a shaping device comprising the steps of:

selecting one or more of a plurality of removable sections; and

removing the one or more selected section(s) thereby changing the size or shape of the shaping device.

144. (Original) The method of Claim 143, wherein the step of removing the one or more selected section(s) comprises detaching said one or more section(s) from the shaping device along a perforation.

145. (Original) The method of Claim 144, wherein said perforation comprises a thin or weak wall area.

146. (Original) A method for treating ischemic congestive heart failure in a patient comprising the steps of:

identifying akinetic tissue within a heart chamber wall;

making an incision through the akinetic tissue in the chamber wall;

inserting a shaping device into the chamber through the incision, said shaping

device comprising one or more guide marks configured to aid the practitioner;

removing the shaping device; and

closing the incision.

147. (Original) The method of Claim 146, wherein said guide marks on said shaping device are configured to aid in positioning the shaping device.

148. (Original) The method of Claim 146, wherein said guide marks on said shaping device are configured to aid in placing a suture line.

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149. (Original) The method of Claim 146 further comprising the step of at least partially securing to the chamber wall a patch, wherein said guide marks on said shaping device are configured to aid in selecting an appropriately sized patch.

150. (Original) The method of Claim 146, wherein said shaper comprises a compliant material.

151. (Original) The method of Claim 146, wherein said shaper is configured to self-expand.

152. (Original) The method of Claim 146, wherein said shaper does not require inflation.

153. (Original) The method of Claim 146, wherein said shaper requires inflation.

154. (Original) A device for treating cardiac afflictions comprising a shaper configured to define a more optimal shape of a heart chamber, wherein said shaper comprises one or more guide marks configured to aid the practitioner.

155. (Original) The device of Claim 154, wherein said guide marks on said shaping device are configured to aid in positioning the shaping device.

156. (Original) The device of Claim 154, wherein said guide marks on said shaping device are configured to aid in placing a suture line.

157. (Original) The device of Claim 154, wherein said guide marks on said shaping device are configured to aid in selecting an appropriately sized patch.

158. (Original) The device of Claim 154, wherein said shaper comprises a compliant material.

159. (Original) The device of Claim 154, wherein said shaper is configured to self-expand.

160. (Original) The device of Claim 154, wherein said shaper does not require inflation.

161. (Original) The device of Claim 154, wherein said shaper requires inflation.

162. (Original) A method for treating ischemic congestive heart failure in a patient comprising the steps of:

identifying akinetic tissue within a heart chamber wall;

making an incision through the akinetic tissue in the chamber wall;

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inserting a shaping device into the chamber through the incision, said shaping device comprising one or more recessed areas configured to avoid damage to anatomical structures;

removing the shaping device; and
closing the incision.

163. (Original) A device for treating cardiac afflictions comprising a shaper configured to define a more optimal shape of a heart chamber, wherein said shaper comprises one or more recessed areas configured to avoid damage to anatomical structures.